DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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December 12, 2014

Osprey Medical, Inc.
Ms. Melanie Hess
Sr. Director, Regulatory
5600 Rowland Road, Suite 250
Minnetonka, MN 55343

Re: K142081
Trade/Device Name: Contrast Monitoring System
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: November 9, 2014
Received: November 12, 2014

Dear Ms. Hess:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142081

Device Name
Contrast Monitoring System

Indications for Use *(Describe)*
The device consists of a manual syringe and display to be used during Angiographic or CT procedures requiring controlled infusion of radiopaque contrast media.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

510(k) Summary As required by 21CFR 807.92(c)

510(k) Number: K142081

Date Prepared:	November 06, 2014
Submitter's Name/Address:	Osprey Medical 5600 Rowland Road Suite 250 Minnetonka, MN 55343
Contact Person:	Melanie Hess Sr. Director, Regulatory Affairs Tel: 952-955-8252 Fax: 952-955-8171 Mhess@ospreymed.com

Device Information:

Trade Name/Proprietary Name:	Contrast Monitoring System
Common Name:	Injector and Syringe, Angiographic
Classification Registration:	21 CFR § 870.1650
Product Code:	DXT
FDA Center/Branch:	CDRH/Interventional Cardiology Devices Branch (ICDB)

Device Description:

The Osprey Medical Contrast Monitoring System (CMS) allows for monitoring and display of manually injected contrast volumes. Volumes are displayed and compared to physician entered contrast usage thresholds during angiographic procedures.

The use of the system is intended to provide the user an easier way to measure cumulated volumes and support physician-determined minimization of contrast volumes. The additional benefit of the system is to allow for a visual and audible indication of when the cumulated volume injected into the patient is approaching a physician determined contrast volume threshold. This allows for attentive physician decision-making of total contrast volumes use during a patient case while allowing the physician's primary focus to remain on the image and the therapeutic need of imaging.

Indications for Use:

The device consists of a manual syringe and display to be used during Angiographic or CT procedures requiring controlled infusion of radiopaque contrast media.

Predicate Device:

The Contrast Monitoring System is substantially equivalent in intended use and method of operation to the Medline Angiographic Control Syringe (K093830). The Contrast Monitoring System is also similar to the ACIST Angiographic Injection System (K993774, K991103 and K000013) in that it also provides a visual touchscreen display, provides proactive monitoring of contrast dosaging and system user indicators. The Contrast Monitoring System is also similar to the commercially distributed Merit Medical Coronary Control Syringe (K875196, Syringe, Piston; 21 CFR 880.5860, product code FMF) in that it consists of the same materials and has the same intended use; for injections of contrast medium during Coronary or Peripheral Angiography and Angioplasty.

Trade Name/Proprietary Name:	Medline Angiographic Control Syringe
Common Name:	Injector and Syringe, Angiographic
Classification Registration:	21 CFR § 870.1650
Product Code:	DXT
510(k) number(s)	K093830

Comparison to the Predicate Device:

The CMS is substantially equivalent to the Medline Angiographic Control Syringe in that they are both intended to be a manual injection syringe used during angiographic imaging with contrast media.

The fundamental scientific technology is unchanged from the predicate. The intended use is identical to that of the predicate device. And the indications for use statement is substantially equivalent to the

predicate; and those referenced devices categorized under the most recently issued and appropriately matched FDA product codes. In addition, the CMS utilizes a touchscreen monitor display, user-set thresholds and user indicators similar to the ACIST Angiographic Injection System which has the same intended use. The primary modification from the predicate is to allow electronic display and monitoring for a manual injection syringe procedure (i.e. without power injector). The modifications include an addition of a sensor housing, cable and touchscreen display with software to allow the user to program contrast media thresholds and capture contrast media used per injection; per patient. The use of software for contrast volume and user feedback is similar to the ACIST Angiographic Injection System. No new or different questions of safety or effectiveness are raised with the minor modifications.

Summary of Non-Clinical Testing:

Bench testing was performed to support this submission and results demonstrate that the Contrast Monitoring System meets product specification, meets performance requirements and demonstrates substantial equivalence:

- Device performance testing included visual verifications to design specifications, accuracy testing of cumulative and individual injection volume measurement along with display verification, compatibility with AVERT System and testing demonstrating compliance to IEC 60601-1 3rd edition, electrical safety for medical devices and IEC 60601-1-2 (2007) emissions and immunity for non-life supporting equipment through third party testing certification. All testing passed.

- Sterilization – Sterilization conditions have been validated in accordance with *ISO 11135-1:2007, Sterilization of health care products – Ethylene Oxide Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices* to provide a Sterility Assurance Level of 10^{-6}. All testing passed.

- Software development process was in accordance with IEC 62304:2006 Software life cycle process and testing was performed and included verification of all software requirement specifications. All testing passed.

- Simulated Use (Animal and Bench) Design Validation was performed and included the assessment of threshold input, display verification, ease of use, addition and subtraction of injection, pause of the system, record and data storage retrieval verification and human factors (usability). Animal testing was conducted with swine model by three physicians.

- Shelf-life – Distribution and shipping testing was performed per ASTM D4169-09. Testing included visual inspection, display verification of accuracy, dye leak test, seal strength test and functional testing including cumulative and individual injection accuracy. All testing passed.

- Biocompatible testing was performed in accordance with ISO 10993-1:2009 Biological Evaluation of Medical Devices – Part I: Evaluation and Testing. Testing included L929 MEM Elution, Kligman Maximization Test, Intracutaneous Injection, Systemic Injection, Direct and Indirect Contact Hemolysis, Prothrombin Time Assay, Unactivated partial Thromboplastin Time Assay, In-Vitro Hemocompatibility Assay, and USP Physicochemical tests for Plastics. Testing was completed on the representative device with identical materials cleared under premarket notification K875196. All testing passed.

Clinical Testing:

No clinical testing was performed to support this Traditional 510(k) Premarket Notification.

Statement of Equivalence:

The Contrast Monitoring System has substantially equivalent indications for use statement and identical fundamental scientific technology and intended use as the predicate device. Based on this and data collected in accordance with Osprey Medical Quality System Procedure in compliance with EN ISO 13485:2003 *Medical Devices – Quality management systems - requirements for regulatory purposes* and EN ISO 14791:2012 *Risk management for medical devices*, the Contrast Monitoring System has been shown to be substantially equivalent under 21 CFR Part 807 subpart E.